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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,311	06/20/2003	Eric Adam	SYR-AKT3-5001-C1	5023
32793	7590	09/28/2006	EXAMINER	
TAKEDA SAN DIEGO, INC. 10410 SCIENCE CENTER DRIVE SAN DIEGO, CA 92121			NASHED, NASHAAT T	
			ART UNIT	PAPER NUMBER
			1656	

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/601,311

**Applicant(s)**

ADAM ET AL.

**Examiner**

Nashaat T. Nashed, Ph. D.

**Art Unit**

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,9,12-15 and 17-30 is/are pending in the application.
- 4a) Of the above claim(s) 17-28 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,9,12-15 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/14/06</u> . | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1656

The application has been amended as requested in the communication filed July 17, 2006. Accordingly, claims 2, 3, 7, 8, 10, 11, and 16 have been canceled, claims 1, 4, 9, and 12-15 have been amended, and new claims 26-30 have been added. Claims 17-25 remain withdrawn from further consideration.

Applicants presented new claims 26-30 as part of elected Group I with traverse. The restriction has been traversed in the prior Office action, mailed April 13, 2006, and was made final. Thus, claim 30 is withdrawn from any further consideration. Also, applicants have added new claims 26-28 directed to a method using the structure obtained by the method of claim 15. The method of claim 26 is a different method from that of claim 15 because the two methods have different steps and products. Methods having different steps can be restricted from one another, and therefore, restriction between the method of claims 26-28 and that of claim 15 is proper. Accordingly, claims 26-28 are withdrawn from further consideration. Applicant should be reminded with their right to a rejoinder to a method claims using an allowed product provided they continue to amend the method claims to be of the same scope as that of the product claim.

Claims 1, 4-6, 9, 12-15, and 29 are under consideration.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-6, 9, 12-15, and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons set forth in the prior Office action mailed 4/13/06.

In response to the above rejection, applicant amended the claims to be limited to SEQ ID NO: 4, and argue that the amendment of the claims obviate the rejection.

Applicants' arguments filed July 17, 2006 have been fully considered, but they are found unpersuasive. The claims remain drawn to a genus of crystals, and the specification provides a single species of the claimed genus. The court of Appeals for the Federal Circuit has held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] name chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *UC California v. Eli Lilly* (43 USPQ2d 1398). For claims drawn to genus, MPEP section 2163 states the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings,

Art Unit: 1656

or by disclosure of relevant, identifying characteristics, i.e., structure or physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Also, MPEP section 2163 states that a representative number of species mean that the species, which are adequately described, are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In general, for a species of crystal to be adequately and structurally described, the following must be adequately described: (i) the exact chemical composition of the crystal, i.e., the structure feature of all molecules in the crystal including the amino acid sequence of any protein or nucleic acid, (ii) the space group of the crystal; and (iii) the unit cell dimension of the crystal. The specification teaches only single species of the claimed crystals which is described by the combined limitation of claims 1, 5, and 6. Thus, the specification fails to describe additional representative species of these crystals by any identifying structural characteristics or properties other than the crystal containing the amino acid sequence of SEQ ID NO: 4 having the cell dimension cited in claim 6 in space group cited in claim 5, for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. New claim 29 is included in this rejection because it reads on any composition containing the polypeptide of SEQ ID NO: 4 in solution and in any crystal form.

Claims 1-15 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons set forth in the prior Office action mailed 4/13/06.

In response to the above rejection, applicant amended the claims to be limited to SEQ ID NO: 4, and argue that the amendment of the claims obviate the rejection.

Applicants' arguments filed July 17, 2006 have been fully considered, but they are found unpersuasive. It is well established in the art that obtaining a protein and its complexes in a crystal form is highly unpredictable without any clear expectation of success, and any change in a given crystallization condition including any minor alteration could alter the crystal form and its diffraction characteristics or even lack of crystal formation. It is now evident that protein crystallization is the major hurdle in protein structure determination. For this reason, protein crystallization has become a research subject in and of itself, and is not simply an extension of structure biologist or crystallographer's laboratory. There are many references that describe the difficulties associated with protein crystals. See for example, Gilliland *et al.*, (*Curr. Opin. in Struct. Biol.* 1996, 6, 595-603) in particular page 600, left column second paragraph; Ke *et al.* (*Methods*, 2004, 34, 408-414); and Wiencek, J. M. (*Ann. Rev. Biomed. Eng.* 1999, 1,

Art Unit: 1656

505-534). Applicants have provided no arguments or presented any evidence indicating the teaching of one orthorhombic crystal in space group  $P2_12_12_1$  with the specific unit cell dimension in claim 6 for the protein of SEQ ID NO: 4 grown under specific crystallization condition is sufficient enablement for any crystal of SEQ ID NO: 4 obtained under any crystallization conditions and a method of obtaining said crystal. New claim 29 is included in this rejection because it reads on any composition containing the polypeptide of SEQ ID NO: 4 in solution and in any crystal form.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTWTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen M. Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Nashaat T. Nashed, Ph. D.  
Primary Examiner